



November 19, 2001

**WARNING LETTER NO. 2002-NOL-12**

**FEDERAL EXPRESS**  
**OVERNIGHT DELIVERY**

Mrs. Donna C. Verdin, President  
Four R Enterprise, Inc.  
123 West Bayou Road  
Des Allemands, Louisiana 70030

Dear Mrs. Verdin:

We inspected your firm, located at 123 West Bayou Road, Des Allemands, Louisiana, on October 1 - 2, 10, and 16, 2001, and found that you have serious deviations from seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123), and the Current Good Manufacturing Practice (CGMP) regulations in manufacturing, packing, or holding food for human consumption, 21 CFR 110. These deviations cause your ready-to-eat crabmeat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

During the inspection, the investigator collected samples of your cooked, ready-to-eat crabmeat. The samples were subsequently analyzed for the presence of microorganisms. You should be aware that *Escherichia coli* (*E. coli*) was recovered from two samples, collected on October 1 and 2, 2001, of the cooked, ready-to-eat crabmeat. You may already have received a letter from our Southeast Regional Laboratory in Atlanta, Georgia, notifying you of the same. The presence of *E. coli* causes your crabmeat to be in violation of the Act.

*E. coli* is part of the normal intestinal flora of humans or other primates. The presence of *E. coli* in your crabmeat is an indicator of either undercooked product or insanitary conditions, including poor employee practices, within your facility. Some strains of *E. coli* cause foodborne bacterial illness such as gastroenteritis that can be a serious illness for some people; especially the elderly, newborns, and those with weakened immune systems. Food processors and handlers should take all precautions necessary to reduce the risk of contamination and to keep food safe from *E. coli*. We strongly recommend you determine the cause(s) of this problem and take corrective action as soon as possible.

The deviations were as follows:

- You must have a HACCP plan that lists the critical control points to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for cooked, ready-to-eat crabmeat does not

list the critical control points of crab picking and cooler storage for controlling pathogen growth and toxin formation.

- You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for cooked, ready-to-eat crabmeat does not list the critical limits at the backing and packing critical control points to control pathogen growth and toxin formation.
- You must fully implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of recording the actual cooking time, as listed in your HACCP plan, during the processing of batch # 8 on October 10, 2001.
- You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.8(a). However, your firm did not verify the adequacy of the critical limit of cooking the crabs at [REDACTED] minutes at the cooking critical control point to control pathogen growth.
- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the employee practices with sufficient frequency to ensure control as evidenced by employees wearing earrings during crab cooking and picking operations and not wearing adequate hair restraints. In addition, your firm does not monitor the cleanliness of the food contact surfaces of the equipment used during cooking and backing operations.
- You must take an appropriate corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). However, your firm did not take corrective action to control pathogen growth when you cooked crabs for 10 minutes on October 10, 2001.

In addition, the investigator documented numerous insanitary conditions that cause the crabmeat products you manufacture to be adulterated. Employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination of food with microorganisms or foreign substances. For example:

- Employees routinely contacted unclean equipment, including wet burlap sacks and wooden crates containing live crabs, and then resumed handling cooked crabs without washing or sanitizing their hands; and,
- Employees were observed spraying water on the cook room floor that splashed onto cooked crabs.

Food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated. For example:

- Cooked crabs routinely contacted the following equipment containing residue from previous operations:
  - Metal basket used to cook crabs;
  - Perforated crates used to hold cooked crabs;
  - Reel washer used to wash cooked crabs;
  - Metal cart used to transport perforated crates of cooked crabs; and,
  - Metal stands used to hold perforated crates of cooked, backed crabs.
- The rusty chain of the hoist used to lift baskets of cooked crabs contained an oily substance that contacted the top of the cooking basket; and,
- Cooked crabs routinely contacted the pitted backing table that contained black and brown encrusted residue from previous operations.

You have not taken effective measures to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. Failure to exclude flying pests is a potential contributing factor to microbiological contamination. The following were observed:

- Numerous flies throughout the processing area; directly on windows, walls, trashcans and other potential sources of contaminants;
- Spiders and their webs on the ceiling along the south wall of the area of the facility used during crab backing operations; and,
- One dead roach in the sanitizing solution that was used to sanitize the perforated crates prior to holding cooked crabs.

The inspection found that sanitizing utensils and equipment is not conducted in a manner that protects food and food contact surfaces from contamination. For example, your employees did not sanitize their hands for two hours during picking operations. In addition, the hand sanitizing solutions at two picking stations did not contain any detectable quantity of free chlorine during crab picking operations.

In addition, our investigator documented conditions that facilitate unsanitary operations that are associated with the construction and design of your facility. For example:

- Doors leading into the cooling room did not completely close, allowing flies to freely enter the plant's processing areas from outdoors.
- Two light bulbs suspended over backed, cooked crabs and ice in the cooler of the facility were not protected.

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your product and/or enjoin your firm from operating.

We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within three (3) weeks from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response documentation such as your product HACCP plans, sanitation and process monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the CGMP regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,



Carl E. Draper  
District Director  
New Orleans District

Enclosure: Form FDA 483